

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 430

[Docket No. 97-013F]

RIN 0583-AC46

Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products**AGENCY:** Food Safety and Inspection Service, USDA.**ACTION:** Interim final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its regulations to require that official establishments that produce certain ready-to-eat (RTE) meat and poultry products prevent product adulteration by the pathogenic environmental contaminant *Listeria monocytogenes*. In particular, under these regulations, establishments that produce RTE meat and poultry products that are exposed to the environment after lethality treatments and that support the growth of *L. monocytogenes* will be required to have, in their hazard analysis and critical control point (HACCP) plans, or in their sanitation standard operating procedures or other prerequisite programs, controls that prevent product adulteration by *L. monocytogenes*. The establishments must share with FSIS data and information relevant to their controls for *L. monocytogenes*. The establishments also must furnish FSIS with information on the production volume of products affected by the regulations. The establishments may make claims on the labels of their RTE products regarding the processes they use to eliminate or reduce *L. monocytogenes* or suppress or limit its growth in the products.

DATES: This interim final rule is effective on October 6, 2003.

Comments on the information presented under "Paperwork Reduction Act" must be received by August 5, 2003.

Recognizing, however, that some approaches to *L. monocytogenes* control set out in this interim final rule are novel, FSIS will accept comments on the rule until December 8, 2004, for the purpose of reviewing and evaluating the effectiveness of these approaches.

ADDRESSES: One original and two copies of each comment should be sent to FSIS Docket #97-013F, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102 Cotton Annex, 300 12th Street, SW., Washington, DC 20250-3700. Comments will be

available for public inspection in the Docket Clerk's Office between 8:30 and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Acting Assistant Deputy Administrator, Policy Analysis and Formulation, Office of Policy, Program Development, and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture (202) 205-0495. Copies of references cited in this document are available in the FSIS Docket Clerk's Office, Room 102, Cotton Annex, 300 12th Street, SW., Washington DC 20250-3700. The Office is open 8:30 a.m. to 4:30 p.m., Monday through Friday.

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I. Background

The Food Safety and Inspection Service (FSIS) administers the Federal Meat Inspection Act (FMIA; 21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA; 21 U.S.C. 451 *et seq.*) to ensure that meat, poultry, and egg products prepared for distribution in commerce are wholesome, not adulterated, and properly marked, labeled, and packaged. The FMIA and PPIA prohibit anyone from selling, transporting, offering for sale or

transportation, or receiving for transportation in commerce, any adulterated or misbranded meat or poultry product (21 U.S.C. 610, 458).

Under the Acts, a meat or poultry product is adulterated if, among other circumstances, it bears or contains any poisonous or deleterious substance that may render it injurious to health (21 U.S.C. 601(m)(1), 453(g)(1)); if it is for any reason unsound, unhealthful, unwholesome, or unfit for human food (21 U.S.C. 601(m)(3), 453(g)(3); or if it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health (21 U.S.C. 601(m)(4), 453(g)(4). Such a product is misbranded if, among other circumstances, it fails to bear directly or on its container the official inspection legend (*e.g.*, for meat products, "U.S. Inspected and Passed" plus the official establishment number) prescribed in the regulations (21 U.S.C. 601(n)(12), 453(h)(12)). The Acts require FSIS to carry out an inspection of meat, meat food products, and poultry products to ensure that the products are not adulterated (21 U.S.C. 606, 455), and if the products are found upon inspection to be not adulterated, they must bear directly or on their containers the official inspection legend (21 U.S.C. 606, 607, 457).

The Acts give FSIS broad authority to promulgate such rules and regulations as are necessary to carry out the Acts (21 U.S.C. 621, 463). The Acts require FSIS to prescribe rules and regulations governing the sanitary conditions under which the establishments that produce these products are to be operated (21 U.S.C. 608, 456).

On February 27, 2001, FSIS proposed (66 FR 12589) to establish several new requirements for the processing of ready-to-eat (RTE) and other meat and poultry products. The Agency proposed food safety performance standards for all RTE and all partially heat-treated meat and poultry products. The proposed performance standards set both levels of pathogen reduction and limits on pathogen growth that official meat and poultry establishments must achieve in order to produce products that are not adulterated. FSIS also proposed to allow the use of customized, plant-specific processing procedures and to eliminate its regulations that require that both RTE and not-ready-to eat pork and products containing pork be treated to destroy trichina (*Trichinella spiralis*).

Finally, FSIS proposed environmental testing requirements intended to verify measures to reduce the incidence of *L. monocytogenes* in RTE meat and poultry products. Specifically, FSIS proposed to